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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/776,252	02/02/2001	Andrew Ellington	D 6 2 9 6	9740

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EXAMINER

FORMAN, BETTY J

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 03/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/776,252

Applicant(s)

ELLINGTON, ANDREW

Examiner

BJ Forman

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 29-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 29-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 21 December 2005 has been entered.

### ***Status of the Claims***

2. This action is in response to papers filed 21 December 2005 in which claim 1 was amended and a Declaration under 37 C.F.R. § 1.131 was submitted.

The previous rejections in the Office Action dated 21 June 2005 over Stanton et al are withdrawn in view of the Declaration. The previous rejections over Royer are withdrawn in view of Applicant's comments on page 5 of the response. Applicant's arguments have been thoroughly reviewed but are deemed moot in view of the amendments, withdrawn rejections and new grounds for rejection. New grounds for rejection are discussed.

Claims 29-43 are under prosecution.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent

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or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 29-37 and 40-43 are rejected under 35 U.S.C. 102(e) as being anticipated by Gold et al (U.S. Patent No. 6,242,246, filed 15 December 1997) as defined by Pitner et al (U.S. Patent No. 5,650,275, issued 22 July 1997).

Regarding Claim 29, Gold et al disclose a method of transducing a conformational change in a signaling aptamer, the method comprising the steps of providing a signaling aptamer (reporter molecule covalently coupled to an aptamer, i.e. the labeled aptamer is prepared by methods taught by Pitner, U.S. Patent No. 5650275, Column 15, lines 44-59) wherein unbound signaling aptamer is quenched relative to the signal when aptamer undergoes a conformational change upon binding its ligand (Column 13, lines 37-59 and Fig. 5). The method further comprises, containing the signaling aptamer with the ligand for binding and detecting signal produced by the reporter (Column 13, lines 37-59 and Fig. 5). Gold et al teach the labeled signaling aptamer is prepared by methods taught by Pitner, U.S. Patent No. 5,650,275 (Column 15, lines 44-59). Pitner defines the ligand labeling as covalent (Column 5, lines 7-9). Because Gold et al teaches the signaling aptamers are labeled using the method of Pitner and because Pitner teaches the aptamer is covalently coupled to the aptamer, Gold et al anticipates the covalently coupled aptamer-reporter as claimed.

Regarding Claim 30, Gold et al disclose the method further comprising quantifying the amount of label bound to the aptamer (Column 15, lines 57-65).

Regarding Claim 31, Gold et al disclose the method wherein the optical signal is fluorescence, anisotropy, polarization, lifetime or intensity (Column 15, lines 57-65).

Regarding Claim 32, Gold et al disclose the method wherein the covalent coupling occurs during synthesis (Column 15, lines 44-47) as defined by Pitner (Column 7, lines 11-19).

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Regarding Claim 33, Gold et al disclose the method wherein the reporter is a dye (e.g. Column 15, lines 52-57).

Regarding Claim 34, Gold et al disclose the method wherein the dye is a fluorescent dye (e.g. Column 15, lines 52-57).

Regarding Claim 35, Gold et al disclose the method wherein the dye is attached according to the method of Pitner (Column 15, lines 44-47) and Pitner defines the dye attachment as insertion of a fluorescein at an internal position (Column 4, lines 32-43).

Regarding Claim 36, Gold et al disclose the method wherein the dye is acridine or fluorescein (e.g. Column 15, lines 52-57).

Regarding Claim 37, Gold et al disclose the method wherein the aptamer comprises modified or unmodified RNA or DNA (nucleic acid ligands, Column 5, lines 56-58) wherein nucleic acids are modified or unmodified RNA or DNA (Column 5, lines 23-43).

Regarding Claim 40, Gold et al disclose the method wherein the label is adjacent to a functional residue (i.e. "within the binding site of the target molecule, Column 16, lines 1-3) wherein the label is attached according to the method of Pitner (Column 15, lines 44-47) and Pitner defines the dye attachment as insertion of a fluorescein at an internal position (Column 4, lines 32-43).

Regarding Claim 42, Gold et al disclose the method wherein the aptamer is in solution i.e. the aptamer is crosslinked so that "interaction with target molecules will occur in solution" (Column 9, lines 8-12).

Regarding Claims 42-43, Gold et al disclose the method wherein the aptamer is immobilized on a chip (Column 13, lines 37-59 and Fig. 5).

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 38-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gold et al (U.S. Patent No. 6,242,246, filed 15 December 1997) as defined by Pitner et al (U.S. Patent No. 5,650,275, issued 22 July 1997) in view of Szostak et al. (U.S. Patent No. 5,631,146, issued 20 May 1997).

Regarding Claim 38-39, Gold et al disclose a method of transducing a conformational change in a signaling aptamer, the method comprising the steps of providing a signaling aptamer (reporter molecule covalently coupled to an aptamer, i.e. the labeled aptamer is prepared by methods taught by Pitner, U.S. Patent No. 5650275, Column 15, lines 44-59) wherein unbound signaling aptamer is quenched relative to the signal when aptamer undergoes a conformational change upon binding its ligand (Column 13, lines 37-59 and Fig. 5). The method further comprises, containing the signaling aptamer with the ligand for binding and detecting signal produced by the reporter (Column 13, lines 37-59 and Fig. 5).

Gold et al teach their method is useful for detecting a variety of ligands for diagnosis of numerous important ligand-specific diseases (Column 7, line 48-Column 8, line 13) but they do not teach the aptamers are anti-adenosine RNA or DNA aptamer wherein the former is ATP-R-ACI3 and the latter is DFL7-8 and the ligand (target molecule) is adenosine.

However, Szostak et al teach anti-adenosine triphosphate and anti-adenosine DNA aptamers prepared by the same process (Column 4, line 56-column 6, line 9) and they further teach anti-adenosine aptamers are especially useful for ATP purification and in vivo quantification (Column 18, lines 31-42). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply anti-adenosine aptamers of Szostak et al to the target detection of Gold et al for the expected benefits of purification and in

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vivo quantification of an important target molecule as taught by Szostak et al (Column 18, lines 31-42).

### **Conclusion**

7. No claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

  
BJ Forman, Ph.D.  
Primary Examiner  
Art Unit: 1634  
February 24, 2006